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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,890	01/13/2004	H. Phillip Koeffler	066783-0144	3623
<div>41552 7590 09/20/2007</div> <div>MCDERMOTT, WILL & EMERY</div> <div>4370 LA JOLLA VILLAGE DRIVE, SUITE 700</div> <div>SAN DIEGO, CA 92122</div>				
			<div>EXAMINER</div> <div>HUGHES, ALICIA R</div>	
			<div>ART UNIT</div> <div>1614</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>09/20/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/756,890	Applicant(s) KOEFFLER ET AL	
	Examiner Alicia R. Hughes	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-115 is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67, 69, 70, 74, 76, 78, 80, 81, 83, 85, 87, 95-97, 101, 103, 105, 107, 108, 110, 112 and 114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 61-66,68,71-73,75,77,79,82,84,86,88-94,98-100,102,104,106,109,111,113 and 115.

DETAILED ACTION

Status of the Claims

Claims 67, 69, 70, 74, 76, 78, 80, 81, 83, 85, 87, 95-97, 101, 103, 105, 107-108, 110, 112, and 114 are pending and the subject of this Office Action. Claims 61-66, 68, 71-73, 75, 77, 79, 82, 84, 86, 88-94, 98-100, 102, 104, 106, 109, 111, 113, and 115 are withdrawn from consideration, being drawn to a non-elected invention. See 37 C.F.R. 1.142(b).

Applicants' arguments and amendments filed on 27 August 2007 in response to the non-final rejection filed by this Office on 27 February 2007 have been fully considered, but they are not deemed to be persuasive. Rejections and objections not reiterated from previous office actions are hereby withdrawn. The following rejections are reiterated and expounded upon, and they constitute the complete set presently being applied to the instant application, hereby making this rejection FINAL.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67, 69, 83, 85, 95-96, 110, and 112, are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/30430 A1 [hereinafter referred to as "Blanchard, et al"] in view of U.S. Patent No. 6624138 [hereinafter referred to as "Sung, et al"] and in further view of ElGenidi, M., *Prevention of Chemotherapy-Induced Alopecia by the New Digital Scalp Cooler Device* (Abstract), European Journal of Cancer, vol. 37, supplement 6, April 2001, page S357 (abstract page 1)[hereinafter referred to as "ElGenidi"]

Claims 67, 69, 70, 76, 80, 81, 87, 95-97, 103, 107-108, and 114 are rejected under 35 U.S.C. 103(a) as being obvious over Blanchard, et al in view of U.S. Patent No. 7001888 [hereinafter referred to as "Tidmarsh et al.], in further view of Sung, et al and in further view of ElGenidi.

Claims 67, 69, 74, 78, 95-96, 101, and 105 are rejected under 35 U.S.C. 103(a) as being obvious over Blanchard, et al in view of U.S. Patent No., 5795909 [hereinafter referred to as Shashoua et al.], in further view of Sung, et al and in further view of ElGenidi.

This Office's arguments related to all 35 U.S.C. 103(a) rejections in the Office Action of 27 February 2007 are incorporated herein by reference in their entirety.

Applicants argue that the Office has failed to set out a *prima facie* case of obviousness over any of their examined claims, because Blanchard et al, the central reference in the rejections, do not teach or suggest the method claimed, but at best, "describes the use of vitamin D₂ compounds for reducing, preventing or treating hair loss (alopecia) induced by a chemotherapeutic agent," Page 9 of Applicants' Arguments of 27 August 2007, first full

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paragraph, and that Blanchard's deficiencies are not cured by the teachings of either ElGenidi or Sung et al, most notably because Sung et al "describes a solidifiable drug-containing biological material and huge laundry list of numerous exemplary drugs suitable for inclusion in the material, including analgesics, antibiotics, antidepressants, etc." *Id.*

As noted previously, it is known in the art that anti-cancer and chemotherapeutic agents reduce the severity of proliferative disorders associated with cancer. Further, it is known in the art that paricalcitol is an effective treatment for tissues that contain cancerous cells and/or tumors. As a result, when used together, it would be obvious to one of ordinary skill in the art that the proliferation of cancers and their associated tumors would be diminished.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine paricalcitol with PS341, dexamethasone, daunomycin, arsenic trioxide, taxol, or methotrexate to reduce the severity of proliferative disorders.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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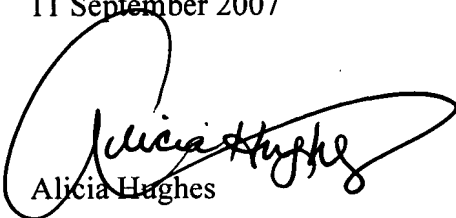
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571.272.6026. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571.272.0718. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11 September 2007


Alicia Hughes


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER